UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF ILLINOIS

	X
IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	: 3:09-md-02100-DRH-PMI : MDL No. 2100
ZAYKEYA THOMAS-COLES, Plaintiff	: Judge David R. Herndon: COMPLAINT AND. JURY DEMAND
vs.	•
BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG,	: Civil Action No.: 3:12-cv-10523-DRH-PMF :
Defendants.	:
	: X

Plaintiff, by her attorneys, TorHoerman Law LLC, on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

- 1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.
- 2. Plaintiff is filing this Complaint as permitted by Case Management Order #9 issued by Judge David R. Herndon of this Court. Plaintiff states that but for that Order permitting direct filing into the Southern District of Illinois, Plaintiff would have filed in the

United States District Court for the District of New Jersey. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the District of New Jersey as set forth in Case Management Order #9.

3. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2100 as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of New Jersey, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of New Jersey and the State of Illinois unrelated to Plaintiff's claims.

PARTY PLAINTIFF

- 4. Plaintiff, Zaykeya Thomas-Coles, is a citizen of the United States of America, and is a resident of Union County, New Jersey.
- 5. Plaintiff, Zaykeya Thomas-Coles, first began using Yaz and/or Yasmin in or around February 2010 and stopped using Yaz and/or Yasmin in or around May 2010.
- 6. As result of using Defendants' Yaz and/or Yasmin, Plaintiff Zaykeya Thomas-Coles, was caused to suffer a aallbladder injury in or about May 2010, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.
- 7. The injuries and damages sustained by Plaintiff, Zaykeya Thomas-Coles, were caused by Defendants' Yaz and/or Yasmin.
- 8. Plaintiff did not know, and could not have known, that her injuries were caused by a defective product until at least May of 2010.

PARTY DEFENDANTS

9. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

- 10. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.
- 11. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. has transacted and conducted business in the State of Illinois and in the State of New Jersey, and derived substantial revenue from interstate commerce.
- 12. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. expected or should have expected that its acts would have consequences within the United States of America, in the State of New Jersey, and in the State of Illinois, and derived substantial revenue from interstate commerce.
- 13. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of approved New Drug Application No. 21-676 for YAZ.
- 14. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. markets YAZ and Yasmin in the United States.
- 15. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is a pharmaceutical company domiciled in Germany.
- 16. Defendant BAYER SCHERING PHARMA AG is formerly known as Schering AG and is the same corporate entity as Schering AG.
- 17. Upon information and belief, Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

- 18. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin.
- 19. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.
- 20. Defendant BAYER SCHERING PHARMA AG manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in YAZ, Yasmin and Ocella.
- 21. Upon information and belief, Defendant BAYER SCHERING PHARMA AG has transacted and conducted business in the State of Illinois and in the State of New Jersey, and derived substantial revenue from interstate commerce.
- 22. Upon information and belief, Defendant BAYER SCHERING PHARMA AG expected or should have expected that its acts would have consequences within the United States of America, in the State of New Jersey, and in the State of Illinois, and derived substantial revenue from interstate commerce.
- 23. Upon information and belief, and at all relevant times Defendant BAYER SCHERING PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.
- 24. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.
- 25. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such,

Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

- 26. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin.
- 27. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of Illinois and in the State of New Jersey, by selling and distributing its products in the State of Illinois and engaged in substantial commerce and business activity in the State of Illinois and in the State of New Jersey.
- 28. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New York.
- 29. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Illinois and in the State of New Jersey, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC and as such, for purposes of establishing diversity of citizenship, Defendant BAYER HEALTHCARE LLC is a citizen of Indiana and Pennsylvania.
- 30. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America, in the State of Illinois, and in the State of New Jersey, and derived substantial revenue from interstate commerce.

- 31. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.
- 32. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER SCHERING PHARMA AG.
- 33. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Illinois and in the State of New Jersey, and derived substantial revenue from interstate commerce.
- 34. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, in the State of Illinois, and in the State of New Jersey, and derived substantial revenue from interstate commerce.
- 35. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over **Defendants** BAYER CORPORATION, **BAYER** LLC, **HEALTHCARE** HEALTHCARE BAYER PHARMACEUTICALS, INC., and BAYER SCHERING PHARMA AG.
- 36. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.
- 37. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

- 38. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.
- 39. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Illinois and in the State of New Jersey, and derived substantial revenue from interstate commerce.
- 40. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, in the State of New Jersey, and in the State of Illinois, and derived substantial revenue from interstate commerce.
- 41. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.
- 42. Defendants, BAYER HEALTCHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG shall, hereinafter, be collectively referred to as "Bayer" or "Defendants."

NATURE OF THE CASE

Bayer's Combined Oral Contraceptives – Yasmin and Yaz

- 43. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.
- 44. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

- 45. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.
- 46. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.
- 47. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.
- 48. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.
- 49. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

- 50. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.
- 51. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.
- 52. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.
- 53. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.
- 54. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.
- 55. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.
- 56. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
- 57. Additionally, a dangerous effect of drospirenone is that it acts as a diuretic, which travels into the kidney, and blocks the aldosterone receptors. Aldosterone is a hormone that

increases the reabsorption of sodium and water and the secretion of potassium in the kidneys, resulting in dehydration. Dehydration, may lead to the formation of gall stones. Blocking the aldosterone receptor may also increase the levels of cholesterol in the blood. An excess of cholesterol, calcium and phosphate in the gallbladder reduces gallbladder emptying and results in gallbladder disease.

- 58. Upon information and belief, Defendants knew or should have known that the use of drospirenone in Yasmin and Yaz is known to cause gallbladder disease, which requires surgical intervention.
- 59. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.
- 60. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.
- 61. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.
- 62. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.
- 63. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.
 - 64. Some deaths reported occurred in women as young as 17 years old.

65. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

Over-Promotion of Yasmin and Yaz

- 66. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.
- 67. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.
- 68. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."
- 69. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"
- 70. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."
- 71. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the more serious condition of premenstrual dysphoric disorder or "PMDD."
- 72. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

- 73. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."
- 74. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."
- 75. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.
- 76. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yaz and/or Yasmin and Resulting Injuries

- 77. As a result of Defendants' claim regarding the effectiveness and safety of Yaz and/or Yasmin, Plaintiff Zaykeya Thomas-Coles's medical provider prescribed and Zaykeya Thomas-Coles began using Yaz and/or Yasmin in or around February 2010. Plaintiff Zaykeya Thomas-Coles continued using Yaz and/or Yasmin until May 2010. In May 2010, Plaintiff Zaykeya Thomas-Coles was diagnosed with a gallbladder injury.
- 78. As a direct and proximate result of using Yaz and/or Yasmin, Plaintiff Zaykeya Thomas-Coles suffered the injuries described above.

- 79. Prior to Plaintiff's use of Yaz and/or Yasmin, Defendants knew or should have known that use of Yaz and/or Yasmin created a higher risk of serious personal injury than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.
- 80. Therefore, at the time Plaintiff used Yaz and/or Yasmin, Defendants knew or should have known that the use of Yaz and/or Yasmin created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, development of gall bladder disease and even death.
- 81. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz and/or Yasmin, Defendants failed to adequately warn Plaintiff Zaykeya Thomas-Coles and/or her health care providers of said serious risks before she used the products.
- 82. Had Plaintiff Zaykeya Thomas-Coles and/or her heath care providers known of the increased risks and dangers associated with Yaz and/or Yasmin, she would not have used the product and would not have suffered a gallbladder injury in Ma of 2010.
- 83. As a direct and proximate result of her use of Yaz and/or Yasmin, Plaintiff Zaykeya Thomas-Coles has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including, but not limited to, suffering from a Gallbladder injury, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which will affect her throughout her lifetime.
- 84. Further, as a direct and proximate result of her use of Yaz and/or Yasmin, Plaintiff Zaykeya Thomas-Coles has suffered significant mental anguish and emotional distress

and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

85. Plaintiff Zaykeya Thomas-Coles has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yaz and/or Yasmin.

FIRST CAUSE OF ACTION

Strict Products Liability Defective Manufacturing

- 86. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.
- 87. Defendants were the manufacturers, designers, distributors, sellers, and/or suppliers of Yaz and/or Yasmin.
- 88. Defendants' Yaz and/or Yasmin was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications.
- 89. As a direct and proximate result of Plaintiff Zaykeya Thomas-Coles use of Yaz and/or Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants, as well as Defendants' failure to comply with federal requirements and standards, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.
- 90. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiff, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability Defect in Design or Formulation

- 91. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.
- 92. Defendants' Yaz and/or Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce, was defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.
- 93. The foreseeable risks associated with the design or formulation of Defendants' Yaz and/or Yasmin include, but are not limited to, the fact that the design or formulation of Defendants' Yaz and/or Yasmin was more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.
- 94. As a direct and proximate result of Plaintiff Zaykeya Thomas-Coles's use of Yaz and/or Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants, as well as Defendants' failure to comply with federal requirements and standards, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.
- 95. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiff, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability Defect Due to Inadequate Warning

- 96. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.
- 97. The Yaz and/or Yasmin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants was defective due to inadequate warning or instruction because the Defendants knew or should have know that the product was unreasonably dangerous by creating significant risks of serious bodily harm and death to consumers, including Plaintiff Zaykeya Thomas-Coles, and they failed to adequately warn consumers and/or their health care providers of such risks.
- 98. The Yaz and/or Yasmin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by the Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of Yaz and/or Yasmin, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious bodily harm and death.
- 99. As a direct and proximate result of this defective product, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.
- 100. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiff, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Strict Products Liability Defect Due to Failure to Adequately Test

- 101. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 102. Defendants advised consumers and the medical community that Yaz and/or Yasmin contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yaz and/or Yasmin versus other oral hormonal birth control pills.
- 103. Had Defendants adequately tested the safety of Yaz and/or Yasmin versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and her physician would not have prescribed, Yaz and/or Yasmin.
- 104. As a direct and proximate result of Defendants' failure to adequately test the safety of Yaz and/or Yasmin versus other oral hormonal birth control pills, Plaintiff Zaykeya Thomas-Coles suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.
- 105. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Negligence

106. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

- 107. Defendants owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of Defendants' Yaz and/or Yasmin, including a duty to ensure that its product did not contain contaminants that posed a risk of bodily harm and adverse events, including death.
- 108. Defendants failed to exercise ordinary care in the design, formulation, manufacture, testing, quality assurance, quality control, distribution, marketing, sale, and/or post-sale surveillance of Defendants' Yaz and/or Yasmin in that Defendants knew or should have known that Defendants' Yaz and/or Yasmin could cause such significant bodily harm and death and was not safe for administration to consumers.
- 109. Despite the fact that Defendants knew or should have known that Defendants' Yaz and/or Yasmin posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Defendants' Yaz and/or Yasmin for administration to patients.
- 110. Defendants knew or should have known that consumers such as Plaintiff Zaykeya Thomas-Coles would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
- 111. As a direct and proximate result of Defendants' negligence, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.
- 112. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiff, so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Breach of Express Warranty

113. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.

- 114. Defendants expressly warranted that Defendants' Yaz and/or Yasmin was of merchantable quality and safe for the use by consumers and users, including Plaintiff Zaykeya Thomas-Coles, for its intended purpose.
- 115. Defendants breached said express warranties in that Defendants' Yaz and/or Yasmin was not safe and fit for its intended use and, in fact, caused debilitating and lethal adverse effects.
- 116. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.

SEVENTH CAUSE OF ACTION

Breach of Implied Warranty

- 117. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.
- 118. At the time Defendants manufactured, marketed, sold, and distributed Yaz and/or Yasmin, Defendants knew of the use for which Defendants' Yaz and/or Yasmin was intended and impliedly warranted that Defendants' Yaz and/or Yasmin to be of merchantable quality and safe for such use.
- 119. Plaintiff Zaykeya Thomas-Coles and her medical providers reasonably relied upon the skill, judgment and representations of Defendants as to whether Defendants' Yaz and/or Yasmin was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.
- 120. Contrary to the implied warranty, Defendants' Yaz and/or Yasmin was unsafe for its intended use and was not of merchantable quality because it was unreasonably dangerous as described herein.

121. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.

EIGHTH CAUSE OF ACTION

Fraudulent Misrepresentation

- 122. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.
- 123. Defendants knowingly and intentionally made material and false and misleading representations to Plaintiff Zaykeya Thomas-Coles, her physicians and to the public that the Defendants' Yaz and/or Yasmin had been tested and was safe and effective.
- 124. Defendants' representations were in fact false, as the Defendants' Yaz and/or Yasmin had not been adequately tested and were not safe and effective.
- 125. Defendants knew, or should have known, that Yaz and/or Yasmin created an unreasonable risk of serious bodily injury or death to consumers.
- 126. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff Zaykeya Thomas-Coles, and the public in general, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense, and/or purchase the subject products, all of which is evidence of callous, reckless and willful disregard for the health, safety and welfare of Plaintiff Zaykeya Thomas-Coles.
- 127. At the time said representations were made by Defendants, and at the time Plaintiff Zaykeya Thomas-Coles used the subject products, Plaintiff Zaykeya Thomas-Coles and/or her medical providers were unaware of the falsity of said representations and reasonably believed them to be true.

- 128. In justifiable reliance upon said representations, Plaintiff Zaykeya Thomas-Coles and/or her medical providers were induced to and did use the subject products, thereby causing Plaintiff Zaykeya Thomas-Coles to suffer severe personal injuries.
- 129. As a direct and proximate result of Defendants' fraudulent concealment and misrepresentations, Plaintiff Zaykeya Thomas-Coles suffered harm, damages, and economic loss.
- 130. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiff, so as to warrant the imposition of punitive damages.

NINTH CAUSE OF ACTION

Violation of New Jersey's Consumer Protection Act

- 131. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein at length.
- 132. At all times relevant, the New Jersey Consumer Fraud Act, N.H. Stat. Ann. §56:8-1, (hereinafter "NJCF") prohibits the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact...in the conduct of any trade or commerce and declares such acts or practices as unlawful.
- 133. Defendants violated the NJCFA by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Yaz/Yasmin. Defendants communicated the purported benefits of Yaz/Yasmin while failing to disclose the serious and dangerous side effects related to the use of Yaz/Yasmin with the intent that consumers, like Plaintiff, and their healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Yaz/Yasmin, respectively.

134. As a result of violating the NJCFA, Defendants caused Plaintiff to be prescribed and to use Yaz/Yasmin, causing severe injuries and damages as previously described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

- 1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial in accordance with Case Management Order #9 issued by United States District Court Judge David R. Herndon.
- 2. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
- 3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- 4. Awarding all applicable statutory damages of the state whose laws will govern this action;
- 5. Awarding Plaintiff reasonable attorneys' fees;
- 6. Awarding Plaintiff the costs of these proceedings; and
- 7. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

RESPECTFULLY SUBMITTED,

Dated: March 20, 2012 /s/ Eric M. Terry

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